DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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July 25, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 03-25

John Phillips, President/Owner
Custom Seafood Services, Inc.
206 Southwest Michigan Street
Seattle, Washington 98106

WARNING LETTER

Dear Mr. Phillips:

On March 20-21, 24, and 28, 2003, we inspected your firm located at 206 Southwest Michigan Street, Seattle, Washington, on March 20, 2003. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342 (a)(4). Accordingly your cooked Dungeness crabmeat and whole crab distributed in vacuum-pulled metal cans is adulterated in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You can find this Act, the Seafood HACCP regulation, and the FDA Fish and Fisheries Products Hazards and Controls Guidance through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." Your firm's HACCP plan for canned Dungeness crabmeat does not list the food safety hazard of *Clostridium botulinum*, which FDA considers to be a food safety hazard that is reasonably likely to occur.

Please note that information regarding the control of *Clostridium botulinum* in vacuum-packaged seafood products can be found in the Fish and Fisheries Products and Hazards Guidance: Third Edition, Chapter 13.

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." Your firm's HACCP plan for cooked dungeness crab fails to include a critical control point at Receiving to control the food safety hazard of pathogen growth and toxin formation. FDA believes that the failure of the plan to list this critical control point demonstrates that the hazard analysis was likely to have been inadequate.

   A critical control point at Receiving would help your firm ensure that ready-to-eat products are consistently cooled at safe temperatures during transport to your firm. This could be done by either requiring records from the transporter monitoring temperatures continuously during transportation or by monitoring the adequacy of the ice or cooling media upon receipt. The ice or cooling media should completely surround the product.

3. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of monitoring the time that the product is exposed to temperatures above 45F at the Picking/Packing critical control point to control the hazard of pathogen growth listed in your HACCP plan for cooked dungeness crabmeat. Specifically, your monitoring records document the temperature of the crabmeat, not the time of exposure. Your monitoring records should document the length of time that product is processed (the time from removal from the cooler until it is placed back in the cooler). Moreover, since you have chosen to monitor internal product temperatures, you must revise your HACCP plan to reflect this monitoring procedure.

4. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for cooked dungeness crab lists a critical limit, "minimum temperature internal [redacted]F", that is inadequate to control pathogen survival.

   FDA does not consider measuring internal temperatures an appropriate method to assure that all of the crabs in each batch have been adequately cooked to destroy pathogens. Variations in temperatures can occur from crab to crab based on crab size and its location

in the cooker. Your critical limit(s) at this critical control point should list the minimum cook temperature and time necessary to achieve a safe cook of all the crabs in the basket. These critical limits should be based on the how full the cooker is and the size of the crabs. Internal temperatures may be used as a verification tool to assure that safe internal temperatures have been achieved, but not as a primary assurance of pathogen destruction.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. Please respond in writing within 15 working days from your receipt of this letter. You may wish to include in your response documentation such as your revised HACCP plan, and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. Your letter of August 14, 2002 does not adequately address the stated deficiencies. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal, Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosures:

Form FDA 483

cc: WSDA with disclosure statement